1st Belarus National BCH Workshop

Biosafety Clearing House Project - Phase III

UN Environment-GEF Project for Sustainable Capacity Building for Effective Participation in the BCH

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Introduction to the Cartagena Protocol on Biosafety (CPB)

Biosafety Clearing House Project - Phase III

UN Environment-GEF Project for Sustainable Capacity Building for Effective Participation in the BCH

- Background
  - CBD, Protocol
- What is the Cartagena Protocol on Biosafety?
  - What is the purpose of the Cartagena Protocol on Biosafety?
  - How does the Cartagena Protocol on Biosafety work?
- Some key elements
  - The Advance Informed Agreement (AIA) procedure: LMOs for intentional introduction into the environment

- Some key elements
  - LMOs for direct use as food or feed, or for processing (LMOs-FFP)
  - Unintentional transboundary movements of LMOs
  - Handling, packaging and identification requirements for LMOs
  - Information-sharing and the Biosafety Clearing-House (BCH), data types, use of data

Origin of the Protocol

CBD Art. 8 (g)

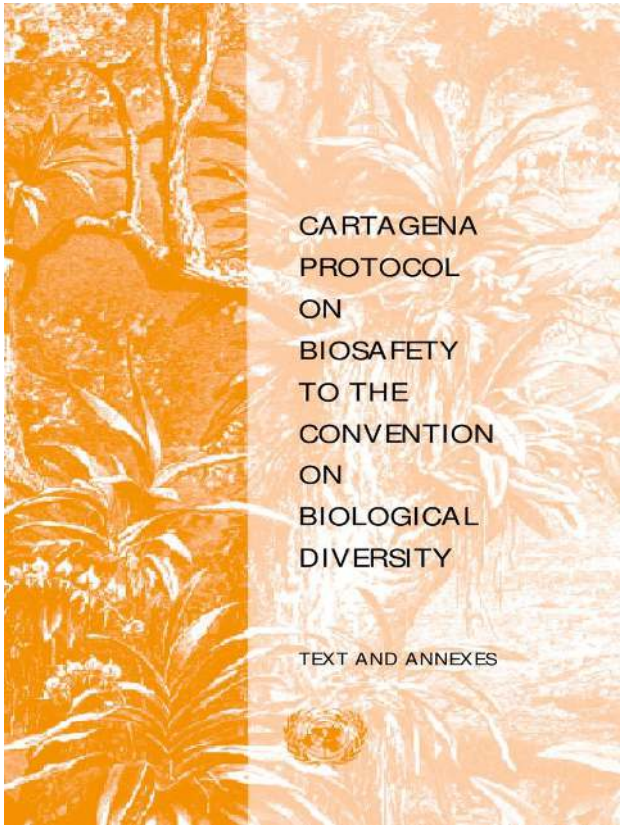
Establish or maintain means to regulate, manage or control the risks associated with the use and release of LMO resulting from biotechnology which are likely to have adverse environmental impacts that could affect the conservation and sustainable use of biological diversity, taking also into account the risks to human health.

Origin of the Protocol

CDB Art. 19.3

The Parties shall consider the need for a protocol setting out appropriate procedures, including, in particular, advance informed agreement, in the field of the safe transfer, handling and use of any LMO resulting from biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity.

What is the Cartagena Protocol on Bioafety?



The Cartagena Protocol on Biosafety is an international agreement (treaty), concluded and adopted in the framework of the Convention on Biological Diversity (CBD)

Objective of the CPB (Art. 1)

Article 1

- The objective of this Protocol is to contribute to ensuring an adequate level of protection in the field of the *safe transfer, handling and use of LMO resulting from modern biotechnology* that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements.

Current Activities

- Adopted 29 January 2000
- Entered into force on September 11, 2003

171 Parties

- Governing body of the Protocol: COP-MOP
  - COP/MOP-1: 23-27 February 2004, KL, Malaysia
  - COP/MOP-2: 30 May-3 June 2005, Montreal, Canada
  - COP/MOP-3: 13-17 March 2006, Curitiba, Brazil
  - COP/MOP-4: 12-16 May 2008, Bonn, Germany
  - COP/MOP-5: 11 - 15 October 2010, Nagoya, Japan
  - COP/MOP-6: 1- 5 October 2012, Hyderabad, India
  - COP/MOP-7: 29 September - 3 October 2014, Pyeongchang, Republic of Korea
  - COP/MOP-8: December, 2016, Cancun, Mexico

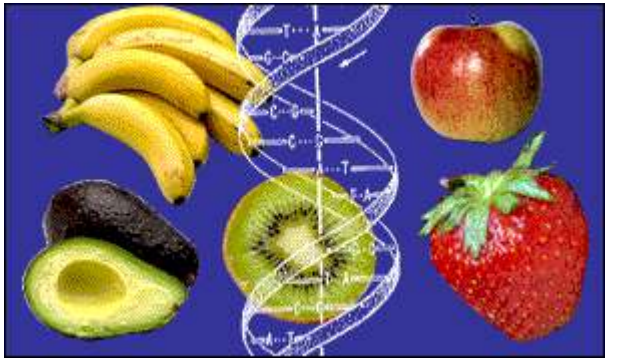
How does CPB work?

- In general terms, the Protocol:
  - a) *Sets out general obligations and principles that are applicable to all LMOs;*
  - b) *Establishes specific rules and procedures that are applicable to the transboundary movement of specific categories of LMOs*
  - c) *Establishes institutional arrangements for the administration, oversight and future evolution of the Protocol; and*
  - d) *Makes provision for capacity building and financial resources to assist developing countries and countries with economies in transition to implement the Protocol.*

Scope of the CPB (Art. 4)

Article 4

This Protocol shall apply to: **transboundary movement, transit, handling and use** of **all living modified organisms** that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health.



LMOs that may have adverse effects

Scope and Application of the CPB

Applies

LMOs for intentional introduction into the environment

LMOs for direct use as a food or feed, or processing.

Does not Apply

LMOs pharmaceuticals for humans addressed in other protocols;

LMOs in transit**,

LMOs for contained use,

LMOs excluded by COP-MOP decissions.

Pharmaceuticals (Art. 5)

Article 5

Protocol shall not apply to the transboundary movement of living modified organisms which are pharmaceuticals for humans that are addressed by other relevant international agreements or organizations.

Transit and Contained Use (Art. 6)

Article 6.1

The advance informed agreement procedure **shall not apply to living modified organisms in transit**.

Transit and Contained Use (Art. 6)

Article 6.2

The provisions of this Protocol with respect to the advance informed agreement procedure **shall not apply to the transboundary movement of LMOs destined for contained use** undertaken in accordance with the standards of the Party of import.

Laboratory

Application of the Advanced Informed Agreement Procedure (Art. 7)

Article 7.1

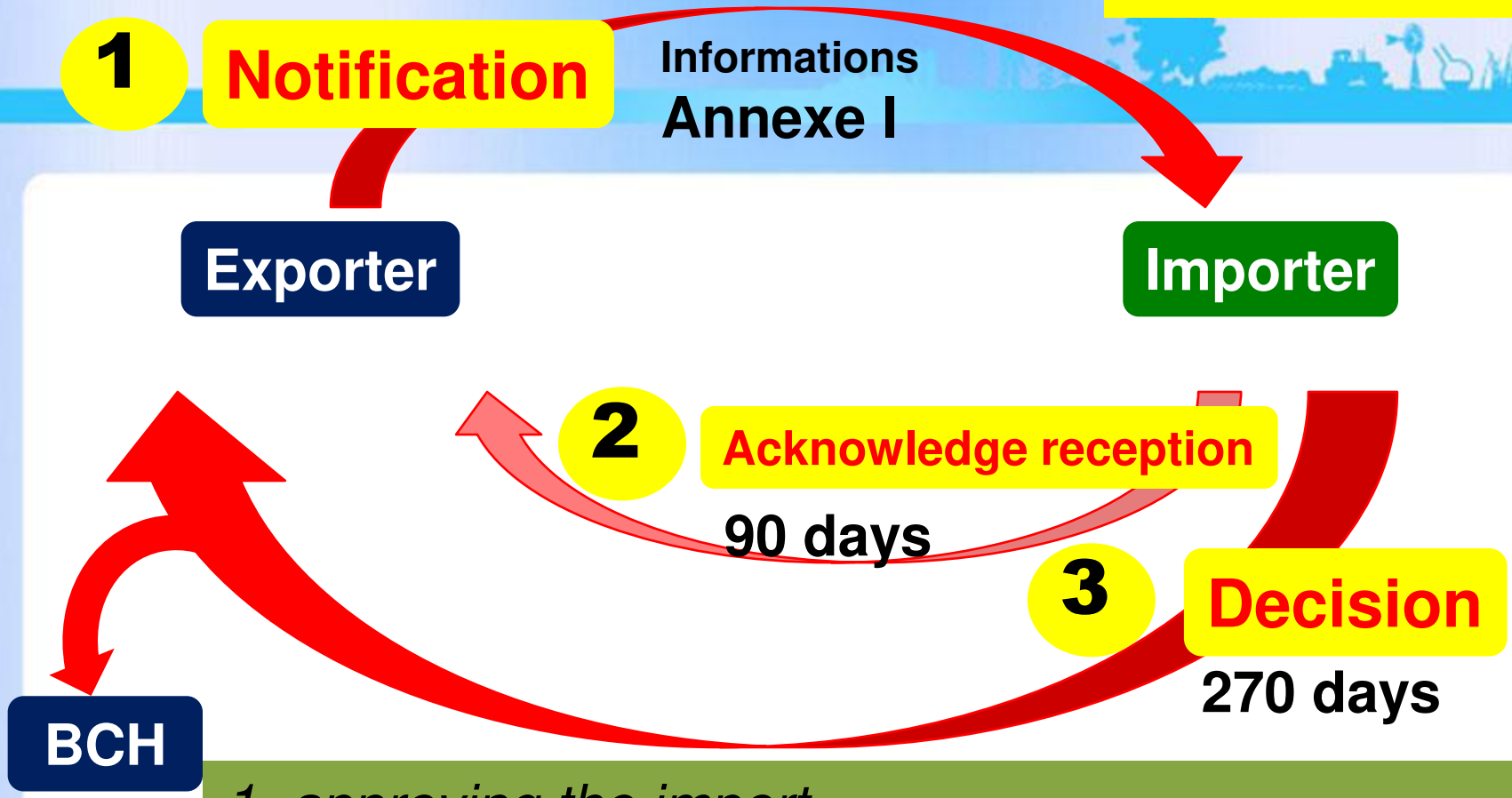
- The advance informed agreement procedure in Articles 8 to 10 and 12 shall apply prior to the first intentional transboundary movement of living modified organisms for intentional introduction into the environment of the Party of import.

Introduction into the environment

AIA Procedure Art. 7 (ctd)

- The advance informed agreement or AIA procedure is designed to ensure that before an LMO is imported into a country for the first time for intentional introduction into the environment, the Party of import:
  - Is notified about the proposed import;
  - Receives full information about the LMO and its intended use;
  - Assess the risks associated with that LMO and to decide whether / or not to allow the import.

AIA Procedure



1. *approving the import,*
2. *prohibiting the import,*
3. *requesting additional relevant information, or*
4. *extending the 270 days by a defined period of time. Unless unconditional consent is given, the Party of import must give reasons for its decision.*

Exceptions to the AIA procedure

- **<u>The Protocol's AIA procedure does not apply to:</u>**
  i. LMOs in **transit [Art. 6];**
  ii. LMOs destined for **contained use [Art. 6] in the Party of import;**
  iii. LMOs intended for direct use as food or feed or for processing (**LMOs-FFP) [Art. 11].**
- Make available to the BCH any decision it takes regarding the transit through its territory of a specific LMO.

LMO intended for direct use as food or feed, or for processing (Art. 11)

- Article 11 refers to LMO that may be subject to transboundary movement for direct use for food, feed or processing.

Article 11

Bulk grains export



LMOs for direct use as food or feed, or for processing (LMOs-FFP)

LMOs for FFP include a large category of agricultural commodities: for example, bulk shipments containing LMO corn, soybeans or other agricultural commodities that are intended for direct use as food or animal feed or for processing, but are not intended for use as seeds.

Procedure for living modified organisms intended for direct use as food or feed, or for processing (Art. 11)

Article 11

- … A Party that makes a final decision regarding domestic use, including placing on the market, of a LMO that may be subject to transboundary movement for direct use as FFP shall, within 15 days of making that decision, inform the Parties through the BCH…

LMO-FFPs and BCH

Article 11.5

- Each Party shall make available to the Biosafety Clearing-House copies of any national laws, regulations and guidelines applicable to the import of LMOs intended for direct use as food or feed, or for processing, if available.
  - Decision regarding commercial growing;
  - Placing on the market of a LMO at the domestic level.

Review of Decision (Art. 12)

Article 12

a) A Party of import may, at any time, in light of new scientific information, **review and change** a decission.

b) A Party of export or a **notifier may also request the Party of import to review its decisions if there is** a change in circumstances or new information becomes available.

Risk Assessment (Art. 15)

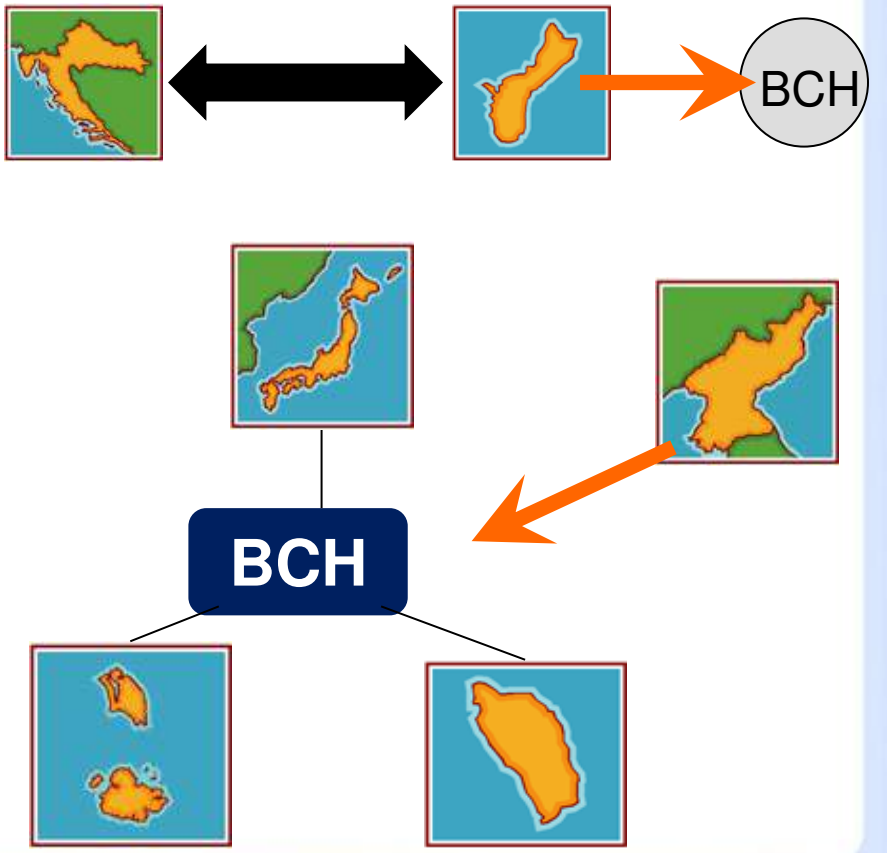
Article 15

- Risk assessments undertaken pursuant to this Protocol shall be carried out in a scientifically sound manner, in accordance with Annex III…

Sharing Decisions

- AIA procedure = bilateral procedure, which is based on direct communication between Parties

- LMO-FFPs procedure = essentially a multilateral information exchange mechanism, centered on the BCH



Competent National Authorities and National Focal Points (Art. 19)

- Upon ratification and entry into force of the Protocol in a country, each Party must:

a) *designate one **National Focal Point (NFP) to be responsible on its behalf for liaison with the Protocol Secretariat (CPB-NFP).***

b) *designate one **National Focal Point for the Biosafety Clearing-House (BCH-NFP) to liaise with** the Secretariat regarding issues of relevance to the development and implementation of the Biosafety Clearing-House.*

c) *provide the BCH with details of its **Point of Contact** for receiving notifications from other Parties of **unintentional transboundary movements of LMOs**.*

d) *notify the Secretariat of the **names and addresses** of its NFP(s) and CNA(s).*

The Biosafety Clearing House

Article 20

A BCH is hereby established as part of the clearing-house mechanism in order to:

a) Facilitate the exchange of Scientific, technical, environmental and legal information on, and experience with, LMOs, and

b) Assist Parties to implement the Protocol, taking into account the special needs of Developing Countries Parties, in particular the least developed and small island developing States among them, and countries with economies in transition as well as countries that are centre of origin and centers of genetic diversity.

Importance of the BCH

- In order to implement the Protocol, Parties, and other entities (e.g. exporters; importers) dealing with LMOs, need access to information about applicable laws and regulations affecting LMOs, and about LMOs themselves.
- The BCH is the primary mechanism through which this information will be available, and is therefore a cornerstone of the Protocol's biosafety regime. The BCH will be particularly important with regard to the transboundary movement of LMO.

Importance of the BCH (2)

- Parties to the Protocol are **obliged** to make certain information available through the BCH. But the BCH also gives countries access to important information provided by others: for example, about relevant national laws and regulations; about decisions other countries have made regarding specific LMOs and about biosafety-related capacity-building initiatives and assistance.

Importance of the BCH (3)

- The Protocol sets out some specific requirements regarding the categories of information to be made available through the BCH. Further specific requirements may also be established in the future by the COP/MOP.
- BCH provides access to other international biosafety information exchange mechanisms.
- It assists Governments to make informed decisions regarding the import or release of LMO.

Parties obligations

Information to be shared no later than entry into force of the Protocol (2/2)

- National Focal Point for the Protocol
- Competent National Authorities and their LMO-related responsibilities
- Article 17 point of contact
- BCH Focal Point

Information to be shared following entry into force (1/2)

- National legislation, regulations and guidelines for implementing the Protocol, as well as information required by Parties for the AIA procedure
- Bilateral, regional and multilateral agreements and arrangements regarding biosafety
- Notification on the application of domestic regulations to specific imports of LMOs
- Imports of LMOs exempted from the AIA procedure
- Cases in which intentional transboundary movement may take place at the same time as the movement is notified to the Party of import
- In the absence of a national regulatory framework , a declaration regarding the framework to be used for the first import of LMO-FFPs

Information to be shared following entry into force (2/2)

- Final decisions regarding the importation or release of LMOs within 15 days of taking the decision for LMO-FFPs and within 270 days of receiving the notification for the AIA procedure.
- Summaries of risk assessments generated by national regulatory process
- Information on review and change of a decision within 30 days of taking the decision
- Notification of a release that leads, or may lead, to an unintentional transboundary movement of a LMO that is likely to have significant adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health
- Information concerning cases of illegal transboundary movements of LMOs

Reference materials

- BCH Central Portal, Cartagena Protocol section
  - http://bch.cbd.int/protocol/
- The Cartagena Protocol text
  - http://bch.cbd.int/protocol/text/
- Manual “Introduction to the Cartagena Protocol”
  - http://bch.cbd.int/help/trainingmaterials/En/03)%20Training%20Modules/MO01En.pdf
- Ready Reference Guides
  - http://bch.cbd.int/help/topics/en/Ready_Reference_Guide.html

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THANK YOU!